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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,506

08/19/2003

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JAB-1281-DIV1

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08/19/2005

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,506

Applicant(s)

BOSMANS ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-7, 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response by applicants dated May 31, 2005 have been entered and considered carefully. Claims 3, 8-9 have been canceled. Claims 1-2, 4-7, 10-13 are pending. The previous office action did not include the preliminary amendment. Therefore the rejections are moot in view of the following new rejections. Applicant's election with traverse of group I in the reply filed on Oct. 27, 2004 is acknowledged. The traversal is on the ground that all the claims have been examined in the parent application. The restriction is therefore withdrawn and all the claims are rejoined.

Claims 1-2, 4-7, 10-13 are examined.

2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "conditions *involving a decreased* gastro-intestinal motility" is ambiguous and confusing. Please note that there is no standard for the term "involving", how much is involving, a little discomfort, sever pain etc. The term is subject to the person to decide how much is involved. The term "decrease" also has no standard since what is decrease to one person may be normal for another.

3. Claims 1-2, 4-7, 10-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term "wherein the -OR4 radical is situated at any position of the central piperidine moiety other than 4 position" lacks antecedent basis in the specification and is NEW MATTER. A survey of the specification indicated on page 2, 7th paragraph, it described "The compounds of the present invention.....the presence of a hydroxyl or a C1-6alkyloxy group on the 3- or 4-position of the central piperidine ring." on page 5 line 16, it was explicitly disclosed that "The

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OR4 radical is preferably situated at the 3- or 4-position of the piperidine moiety.” Therefore, nowhere in the specification support for the instant amendment that the OR4 moiety can be at any other position including 1 and 2 on the piperidine ring. No starting material was disclosed nor was any process of how to make disclosed.

While the compounds can treat pathology or symptom in a patient such as disclosed on page 1, through inhibition of GI motility, there is insufficient description and enablement in the specification for supporting the unknown scope of claim 13 encompassing “conditions *involving a decreased* gastro-intestinal motility”. In addition, treatment of disorders such as irritable bowel syndrome by stimulating gut motility does not necessarily mean a decrease in GI motility is the etiology. Therefore, nexus between the disclosure and the instantly claimed scope is lacking.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-7, 10 and 13 are rejected under 35 U.S.C. 101 because identical claims have been issued as claims 4 and 14 of US 6,452,013 or claim 4 of US 6,635,643 (cited in previous office action)

Claim 4 of US 6,635,643 is identical to the instant claim 6.

Claim 4 and 14 of US 6,452, 013 is identical to the instant claims 1-2, 4-7, and 10.

5. Claims 1-2, 4-7, 10-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of US Patent No. 6,452,013 or over claims 1-10 of US Patent No. 6,635,643 in view of claims 1-15 of US 6,452,013. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are 3-OR4 while the ‘643 claimed the 4-OR4 and the ‘013 claims broadened to include the position isomers i.e. both 3-OR4 and 4-OR4. The issued claims, thus, fully embraced the instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

In view of the repeated issuance of overlapping claims, applicants are requested to show relationship of all copending applications and each issue or pending scope of claims, either directly from the foreign application or as a 371 entry into the national stage.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-7, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Daele et al. US 5,374,637 in view of King et al. US 6,127, 379 supplemented by CA 129 (ES patent date 1997), CA 123, supplemented with CA 131 (showing 5HT4 is for colon activity) (all CA references cited in previous office action).

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Determination of the scope and content of the prior art (MPEP §2141.01)

All references an analogous art of piperidinyl compounds for treating gastrointestinal disorders.

Van Daele et al. '637 disclosed structurally analogous compounds having 5HT activity on gastrointestinal track (see whole article especially examples of table 2).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Van Daele et al. '637 and the instant claims is that the instant claims have the compound with a methylene moiety inserted between the amido linker and the 4-piperidinyl ring. King et al. taught that the conventional one methylene insertion (see In re Ruddy 121 USPQ 427) would give analogous compounds for the same activity (see col. 15, lines 1-10). Supplemented by CA 129, CA 123 and CA 131, which are analogous art since they all disclosed similar compounds for 5HT gastrointestinal activity, such prima facie obvious structural modification indeed gives compounds with similar activity (see CA 129, CA 123 each exemplified compounds with or without the methylene insertion together with variations of R1-R2 ring size, of the OR4 being at 3- or 4- positions).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would be aware of all the pertinent art in the field. The above references places the basic compound structure with the modification of one methylene insertion, in the possession of artisan in the field. The modification of one proven compound with merits of analogous compound for the same utility is considered prima facie obvious. Especially, the modification, supplemented by the factual evidence of CA 129 or 131, are well recognized in the art to be obvious variation having the same pharmacological utility.

Applicants' attention is drawn to that, no certified translation of the priority documents was filed. In addition, CA 129 or CA 131 are factual evidence supporting the prima facie case being concluded employing only prior art.

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-7, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. US 6,127,379 in view of US 5,374,637 and US 5,948,794 supplemented with CA 129, CA 123, CA 131 (see explanation supra).

Determination of the scope and content of the prior art (MPEP §2141.01)

King et al. '379 disclosed structurally analogous compounds for 5HT gastrointestinal activity (see col. 14-16, claims 1-11).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between King et al. '379 and the instant claims is that the piperidinyl ring of the instant claims is OR4 substituted while the King '379 has an unsubstituted piperidinyl ring. Per ponderous of references recited in Van Daele et al. US 5,374,637 vs Van Daele et al. US 5,948,794 showed that the substitution on the piperidinyl ring with or without OR4 is an optional choice for such compounds.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the optional choice of 3- or 4-position OR4 substitution in the possession of artisan in the field. The per ponderous of such variation of the art in similar

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compounds would motivate one skilled in the art to employ such modification since factual evidence supporting prima facie case being concluded are now provided in the field (see CA 129 or 131)

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 17, 2005


Celia Chang
Primary Examiner
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